Keep the FDA Out of Tobacco

Newt Gingrich was right on target when he said that the Food and Drug Administration "had lost its mind" and was "out of control." He said this in response to the Clinton Administration's plan to assert FDA jurisdiction over tobacco products.

The Speaker of the House is not the agency's only critic. Others have criticized the FDA's tendency to overstep its legal bounds: "the mission of the FDA is consumer protection. Unfortunately, the FDA has tended to confuse its mission with the power to promote what it deems to be appropriate personal and professional behavior. The FDA does not have and should not assume a free-ranging charter to improve the well being of individuals."

You might assume that this indictment of the FDA's campaign to expand its jurisdiction to include tobacco would have come from a conservative foe of the Clinton Administration. In fact, Senator Tom Harkin, known as one of the most liberal members of the Senate, made this statement at an April 5, 1995 Labor Committee hearing on the FDA. His statement endorsed the words of a former FDA Commissioner, Dr. Charles Edwards, who had testified at this hearing.

FDA jurisdiction over tobacco would be a disaster. To understand why, a little background would

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be helpful.

Ever since the Surgeon General's first pronouncement that cigarettes were harmful, in 1964, Congress has kept for itself the responsibility for setting national tobacco policy.

Congress' policy, as it has emerged over the past forty years, has four main components. First, adults should be free to choose whether to smoke. Second, the public should be fully informed of the dangers associated with tobacco products through government mandated warning labels. Third, the government should try to reduce tobacco use by means of education and persuasion, but not compulsion. Finally, the government should prevent sales of tobacco products to minors.

The FDA's assertion of jurisdiction over tobacco violates this congressionally mandated policy in a several ways.

First, it is likely to lead to prohibition. The law requires the FDA to certify that the products it regulates are "safe and effective." Since it cannot do so with regard to tobacco, the FDA seems obligated to ban tobacco products entirely.

Second, FDA jurisdiction ignores the clear congressional mandate that the way to address the problem of underage smoking is at the state level. Congress implemented this policy through a 1992 law that provides incentives for states to pass and enforce laws prohibiting sales to minors. State enforcement of minimum age laws, however, has not been given a chance

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by the Clinton Administration. The states are still waiting for final regulations from HHS offering them guidance on how to comply with the 1992 law.

Third, FDA jurisdiction over tobacco violates the clear intent behind the Federal Food, Drug, and Cosmetic Act. That law consistently has been interpreted for decades by both the courts and the Congress to exclude tobacco. In 1971, then FDA Commissioner Charles Edwards said: "The regulation of cigarettes is to be the domain of Congress. . . . Any such move by FDA could be inconsistent with clear congressional intent."

Finally, the FDA's inability to adequately perform its current responsibilities only reinforces the view that it should not have jurisdiction over tobacco. Criticism of the FDA has come from both sides of the aisle in Congress, and the public. Everyone seems to be angered with the slow rate of approval for drugs and medical technology and dissatisfied with the agency's efforts to insure the safety of our food supply.

Handing over tobacco regulation to an agency this beset with problems would have two effects. First, it would ensure that tobacco regulation would be carried out poorly. Second, it would further distract the FDA from its critical job of monitoring food and medical products.

Fortunately, the President's misguided attempt to reduce underage smoking by giving the FDA vast new powers to regulate tobacco is not the only way to

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address the problem. Senator Wendell Ford and Representative Scotty Baesler of Kentucky have introduced legislation that would reduce underage smoking, while avoiding FDA regulation and encouraging enforcement of existing law. These alternatives to the President's plan deserve strong consideration.

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